

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF DELAWARE
3
4 REGENXBIO INC. and THE TRUSTEES)
5 OF THE UNIVERSITY OF)
6 PENNSYLVANIA,)
7 Plaintiffs,) C.A. No. 20-1226-RGA
8 v.)
9 SAREPTA THERAPEUTICS, INC. and)
10 SAREPTA THERAPEUTICS THREE,)
11 LLC,)
12 Defendants.)
13
14 J. Caleb Boggs Courthouse
15 844 North King Street
16 Wilmington, Delaware
17
18 Tuesday, May 2, 2023
19 3:00 p.m.
20 Discovery Dispute Conference
21
22 BEFORE: THE HONORABLE RICHARD G. ANDREWS, U.S.D.C.J.
23
24 APPEARANCES:
25
26 FISH & RICHARDSON
27 BY: SUSAN MORRISON, ESQUIRE
28
29 For the Plaintiff
30
31 MORRIS NICHOLS ARSHT & TUNNELL LLP
32 BY: DEREK FAHNESTOCK, ESQUIRE
33
34 -and-
35
36 QUINN EMANUEL URQUHART & SULLIVAN
37 BY: ANASTASIA M. FERNANDS, ESQUIRE
38
39 For the Defendant

02:51:58

03:03:36 1 Ms. Morrison to sort of tell me where she thought some of
03:03:43 2 the good information might be, and I would see if it was
03:03:46 3 there.
03:03:48 4 So, as I understand it, the notes I made to
03:03:58 5 myself here was that the Plaintiff's theory is that this
03:04:03 6 agreement was relevant to the safe harbor and to damages.
03:04:18 7 And as I sort of understood it, I think the response of the
03:04:24 8 Defendant here was, We provided you with all the information
03:04:30 9 about all of the SRP-9001 that we made.
03:04:45 10 Is that right, Ms. Morrison?
03:04:47 11 MS. MORRISON: I'm sorry, Your Honor. Is it --
03:04:50 12 THE COURT: No, that's all right. You can stand
03:04:52 13 there for a second.
03:04:55 14 Basically, has the Defendant provided you,
03:04:57 15 Here's all the times we made SRP-9001 in the United States
03:05:03 16 and presumably what we have done with it?
03:05:05 17 MS. MORRISON: So, that is -- I believe it's not
03:05:08 18 a hundred percent correct, Your Honor. We still are having
03:05:11 19 a discussion about some batch records. I'm not the closest
03:05:14 20 to that issue on my team, but I believe there's still
03:05:17 21 discussion going on about whether there are some missing
03:05:19 22 batch records and whether we actually have all that
03:05:24 23 information, but that's -- so, I think that's still up for
03:05:29 24 debate. But I think the parties are working on that piece
03:05:31 25 of it in terms of whether we have everything.

02:51:58 1 *** PROCEEDINGS ***
03:01:03 2 DEPUTY CLERK: All rise. Court is now in
03:02:31 3 session. The Honorable Richard G. Andrews presiding.
03:02:31 4 THE COURT: All right. Good afternoon. Please
03:02:33 5 be seated.
03:02:35 6 We're here in the *Trustee of the University of*
03:02:42 7 *Pennsylvania, et al vs Sarepta*.
03:02:45 8 Ms. Morrison, your client, how do you pronounce
03:02:50 9 their name?
03:02:51 10 MS. MORRISON: It's Regenxbio.
03:02:53 11 THE COURT: Regenxbio?
03:02:54 12 MS. MORRISON: Regenxbio.
03:02:55 13 THE COURT: Oh, okay.
03:02:56 14 All right. All right.
03:02:59 15 So, and I see Ms. Morrison there.
03:03:01 16 And Mr. Fahnestock; right?
03:03:06 17 And presumably, you are -- I'm not sure about
03:03:09 18 his handwriting. You are?
03:03:12 19 MS. FERNANDS: Ms. Fernands.
03:03:15 20 THE COURT: Ms. Fernands?
03:03:17 21 MS. FERNANDS: Yes.
03:03:17 22 THE COURT: So, okay. So, I read your letters,
03:03:19 23 and I asked the Defendant to bring along two unredacted
03:03:29 24 versions and two redacted versions.
03:03:32 25 And so, what I had in mind doing was asking

03:05:34 1 MS. FERNANDS: What we have and we've
03:05:36 2 represented to Plaintiffs many times is we have produced a
03:05:41 3 spreadsheet of all batches of SRP-9001 drug product produced
03:05:46 4 prior to the expiration of the patent in November of 2012.
03:05:50 5 As Ms. Morrison has indicated, there are some
03:05:53 6 batch records related to -- they have the spreadsheet of all
03:05:56 7 final product produced. There are some batch records that
03:06:00 8 the manufacturer has not released yet, so my client doesn't
03:06:04 9 have them yet. And we represented that we'll provide those
03:06:08 10 backup batch records as we receive them, but they have the
03:06:10 11 spreadsheet of everything that has been made as of the
03:06:12 12 expiration of the patent.
03:06:14 13 THE COURT: And so, the stuff that was made as
03:06:16 14 of the expiration of the patent, Ms. Fernands, what happened
03:06:27 15 to that stuff?
03:06:28 16 MS. FERNANDS: [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED] there has been no approval yet. The BLA has
03:06:37 19 been submitted and not approved. There's no commercial
03:06:41 20 approval. And so, there are ongoing clinical trials, but,
03:06:47 21 [REDACTED]
03:06:48 22 THE COURT: And so, they're sitting there two
03:06:51 23 years, or I forget what the date was that you said that the
03:06:53 24 patent expired, but maybe not two years, but a decent chunk
03:06:57 25 of time after the patent expired. It's just sitting there.

03:07:06 **1** None of it has ever been sent to Europe, or Japan or some
 03:07:10 **2** other place outside the United States?
 03:07:12 **3** MS. FERNANDS: I don't believe that there have
 03:07:16 **4** been -- [REDACTED], and I believe there's
 03:07:20 **5** been some limited discovery, you know, emails as to that.
 03:07:24 **6** But as far as the clinical trials, those were all run by
 03:07:27 **7** Sarepta, and that information would be with Sarepta, to the
 03:07:32 **8** extent it's being used for clinicals. [REDACTED]

[REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

03:07:53 **13** And so, I don't want to misrepresent that
 03:07:56 **14** nothing's been sent, but there's a trial called the 301
 03:07:59 **15** trial that Sarepta is running that I believe is a global
 03:08:02 **16** trial, but it's a Sarepta trial for FDA submission.
 03:08:06 **17** THE COURT: Well, so maybe a slightly different
 03:08:09 **18** way of asking the same question is essentially: Can you
 03:08:12 **19** account for all the product that has been made?
 03:08:14 **20** MS. FERNANDS: I think I can account for -- I
 03:08:23 **21** don't --
 03:08:23 **22** THE COURT: And when I say that, I don't mean
 03:08:24 **23** you personally, of course. I mean --
 03:08:26 **24** MS. FERNANDS: Right.
 03:08:26 **25** THE COURT: -- in terms of the documentation

03:08:30 **1** that your company, your client, keeps. You know, they know
 03:08:36 **2** how much of it they've made. You've provided a spreadsheet
 03:08:38 **3** to that effect.
 03:08:40 **4** Do they also know, you know, so much of it is
 03:08:44 **5** sitting in the warehouse, so much of it was sent off for a
 03:08:47 **6** trial, so much of it, you know, went bad after sitting
 03:08:52 **7** around for a couple years and we destroyed it, and the
 03:08:57 **8** amount we made is the same amount that we've now accounted
 03:09:01 **9** for?
 03:09:01 **10** MS. FERNANDS: Yes, I'm certain all of that
 03:09:04 **11** information exists, and we have tried to provide that in
 03:09:06 **12** discovery, because not only did we provide what batches were
 03:09:10 **13** made, but we also provided a spreadsheet as to clinical
 03:09:13 **14** trials. Although that could, I think, be updated, but
 03:09:17 **15** there's a second large spreadsheet in the production as to
 03:09:19 **16** what was sent off for clinicals.
 03:09:21 **17** So, yes, that information could be put together
 03:09:24 **18** as to what would happen. I think the relevant question here
 03:09:27 **19** is that this agreement isn't going to speak to what happened
 03:09:29 **20** to it.
 03:09:30 **21** THE COURT: Yeah. So, I understand the question
 03:09:34 **22** I'm asking is not perhaps a hundred-percent germane to why
 03:09:38 **23** we're here.
 03:09:39 **24** So, let me just ask Ms. Morrison: Do you know,
 03:09:43 **25** does your side sort of -- you know, I don't want to ask a

03:09:57 **1** question that asks for your work product, so if you can't
 03:10:03 **2** answer the question without disclosing things you don't want
 03:10:05 **3** to disclose, just tell me.
 03:10:08 **4** But essentially can you account for all the
 03:10:10 **5** product that they've made?
 03:10:11 **6** MS. MORRISON: So, I'm not sure I can answer
 03:10:15 **7** that, Your Honor, but I can answer a slightly different
 03:10:18 **8** question which relates to the relevance of the agreement, if
 03:10:23 **9** that's helpful.
 03:10:24 **10** THE COURT: You guys both want to get me back to
 03:10:26 **11** the agreement. Okay. Well, go ahead. Maybe that's a good
 03:10:29 **12** segue.
 03:10:29 **13** MS. MORRISON: And I want to see if I can --
 03:10:31 **14** would it be helpful if I came to the podium?
 03:10:33 **15** THE COURT: I don't know. I can hear you fine
 03:10:35 **16** from here.
 03:10:35 **17** MS. MORRISON: As long as you can hear me and
 03:10:37 **18** the court reporter can, I'm happy to stay here. The
 03:10:39 **19** agreement -- I think the real sticking point between the
 03:10:42 **20** parties, and I will say that Ms. Fernands and my team did
 03:10:45 **21** try to work this out, and I think the real sticking point,
 03:10:49 **22** and they did offer some unredacted version of the agreement,
 03:10:53 **23** but the real sticking point is something called the joint
 03:10:56 **24** development -- excuse me, the global development plan.
 03:10:59 **25** And I think the issue is this, Your Honor: It's

03:11:03 **1** not so much about -- it is, in part, about what actually was
 03:11:07 **2** made and what happened to it. That's part of the issue.
 03:11:11 **3** But the other part of the issue, of course, is
 03:11:13 **4** what the parties' expectations were as of the date of the
 03:11:17 **5** hypothetical negotiation for damages purposes.
 03:11:20 **6** THE COURT: Well, right. And so, that's a
 03:11:22 **7** damages question.
 03:11:23 **8** MS. MORRISON: Yes.
 03:11:23 **9** THE COURT: The questions I was asking really
 03:11:29 **10** had to do with the safe harbor. And I think the way you
 03:11:34 **11** wrote your letter, you started off with the safe harbor.
 03:11:38 **12** So, I started where you started.
 03:11:39 **13** MS. MORRISON: Okay.
 03:11:39 **14** THE COURT: But is the damages the more
 03:11:46 **15** significant issue?
 03:11:47 **16** MS. MORRISON: I think at this point it perhaps
 03:11:49 **17** is, Your Honor, because the damages issue -- so, our opening
 03:11:54 **18** expert reports for both parties were due this past Friday.
 03:11:57 **19** THE COURT: Okay.
 03:11:58 **20** MS. MORRISON: And so, our damages expert has
 03:12:00 **21** submitted his report or his opening report. He has a reply
 03:12:05 **22** as well. And he relied, in part, on the redacted version of
 03:12:11 **23** the Roche agreement that was produced that's also publicly
 03:12:15 **24** available.
 03:12:16 **25** THE COURT: Right, because it was attached to a

03:12:18 **1** 10K.
 03:12:18 **2** MS. MORRISON: It was attached to a 10K. So, he
 03:12:20 **3** had it, and they also produced that version. And so, he was
 03:12:23 **4** able to rely upon it.
 03:12:25 **5** And in that, he relied upon it because that
 03:12:28 **6** Roche agreement was signed just about, I believe --
 03:12:31 **7** THE COURT: Right, right. I gather it was
 03:12:32 **8** within a month or something.
 03:12:34 **9** MS. MORRISON: Yes, very close to the time of
 03:12:36 **10** the hypothetical negotiation. And so, it's highly relevant
 03:12:39 **11** to the Sarepta negotiator's state of mind coming to the
 03:12:43 **12** hypothetical negotiation about how important having a
 03:12:45 **13** license would be to Sarepta.
 03:12:47 **14** And so, I can't tell Your Honor what is in the
 03:12:53 **15** global development plan because I haven't seen it, but that
 03:12:57 **16** is one area where Regenxbio's facts, we can do nothing more
 03:13:04 **17** than suspect based on what's in the agreement. It's an
 03:13:06 **18** informed suspicion, I would say, that there are items in
 03:13:09 **19** that global development plan that would be relevant to the
 03:13:12 **20** damages analysis because it would inform Sarepta's position
 03:13:16 **21** coming to the hypothetical negotiation. And our damages
 03:13:20 **22** expert did rely pretty extensively on the redacted version
 03:13:25 **23** of the Roche agreement in his expert report.
 03:13:29 **24** And so, we do think it's -- I can't tell you
 03:13:33 **25** what exactly is in these sections that we don't have, of

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03:13:36 **1** course, but I can give you a suspicion of what might be
 03:13:39 **2** there.
 03:13:39 **3** THE COURT: Well, so one of the things that was
 03:13:41 **4** said in the letter and, of course, Sarepta went second, was
 03:13:53 **5** there's a lot of other things in the global development or
 03:13:55 **6** in the agreement, and there were two things in particular.
 03:14:00 **7** One of them was something like exon and the other was
 03:14:04 **8** something else.
 03:14:06 **9** And that, in so many words, there's just a whole
 03:14:13 **10** lot of different things going on at once that have nothing
 03:14:24 **11** to do with the patent and the cultured cells. What in his
 03:14:31 **12** report or her report did your expert do about -- how did
 03:14:36 **13** they address things like that?
 03:14:37 **14** MS. MORRISON: So, I think what you're referring
 03:14:40 **15** to is the portions of the agreement that relate to exon
 03:14:44 **16** skipping and gene editing.
 03:14:46 **17** THE COURT: Okay. Yes.
 03:14:48 **18** MS. MORRISON: So, frankly, those are -- and I
 03:14:50 **19** think we've already said this to Sarepta, those are parts of
 03:14:53 **20** the agreements that we don't -- we're not interested in,
 03:14:57 **21** but -- and we would agree to not have those parts of the
 03:15:02 **22** agreement because they're not particularly relevant. But
 03:15:04 **23** the portions of the agreement our damages expert relied upon
 03:15:08 **24** are specific to the agreement about the gene therapy that is
 03:15:14 **25** made using the patented cultured host cells.

03:15:17 **1** THE COURT: Okay.
 03:15:18 **2** MS. MORRISON: And so -- I'm sorry, Your Honor.
 03:15:19 **3** THE COURT: No, no, no. I thought you were
 03:15:23 **4** pausing there.
 03:15:26 **5** So, why don't we do this. Why don't I get --
 03:15:30 **6** because you could probably point me to in the agreement
 03:15:33 **7** where you think this stuff is that you'd like to have;
 03:15:37 **8** right?
 03:15:38 **9** MS. MORRISON: I certainly can try, Your Honor.
 03:15:40 **10** THE COURT: All right. Well, before you try,
 03:15:42 **11** can we get two redacted and two unredacted, one for me and
 03:15:49 **12** one for my excellent assistant here?
 03:15:53 **13** MS. FERNANDS: Okay. So, when Your Honor asked
 03:15:54 **14** for a highlighted, we actually highlighted the unredacted
 03:15:58 **15** with everything that is redacted.
 03:15:59 **16** THE COURT: Okay. So, in other words -- okay.
 03:16:02 **17** MS. FERNANDS: I think that might be --
 03:16:04 **18** THE COURT: Yeah, yeah. You know --
 03:16:05 **19** MS. FERNANDS: I can also bring an unredacted or
 03:16:08 **20** a clean one.
 03:16:09 **21** THE COURT: No, no. If it's yellow --
 03:16:10 **22** MS. FERNANDS: It is -- I brought three
 03:16:14 **23** different varieties, but I think that might be the most
 03:16:17 **24** efficient way to see what was redacted.
 03:16:19 **25** THE COURT: And so, the yellow is the stuff that

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03:16:21 **1** was redacted?
 03:16:23 **2** MS. FERNANDS: Was redacted from the public
 03:16:24 **3** version, correct.
 03:16:25 **4** THE COURT: So, Ms. Morrison, where would you
 03:16:27 **5** like to direct me to and you better, I guess -- because the
 03:16:32 **6** pagination you have is probably different than the
 03:16:35 **7** pagination of the one I just got.
 03:16:36 **8** MS. MORRISON: It is. And what I have, Your
 03:16:37 **9** Honor, are section numbers --
 03:16:39 **10** THE COURT: Right. So, go ahead.
 03:16:42 **11** MS. MORRISON: -- which are, in some senses,
 03:16:44 **12** partially. So, I'll start with the one -- there's quite a
 03:16:47 **13** few, Your Honor, so I'm not sure how many of these you would
 03:16:50 **14** like me to --
 03:16:51 **15** THE COURT: Well, there's a magic to the number
 03:16:53 **16** three.
 03:16:53 **17** MS. MORRISON: Okay.
 03:16:54 **18** THE COURT: So, why don't you give me your best
 03:16:56 **19** three.
 03:16:56 **20** MS. MORRISON: All right. Let me look at the
 03:16:57 **21** sections that were highlighted for me here.
 03:17:00 **22** So, one that's missing -- we believe is
 03:17:04 **23** partially redacted that's missing information would be
 03:17:09 **24** Section 8.4.1.
 03:17:12 **25** THE COURT: Okay.

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03:17:25	1 MS. MORRISON: And, Your Honor, if I might.	03:20:11	1 be doing together. But there's no way for us to know. And
03:17:27	2 Ms. Fernands --	03:20:15	2 these kinds of issues is why we've been requesting
03:17:27	3 THE COURT: Hold on just one second.	03:20:18	3 production of the full agreement.
03:17:28	4 MS. MORRISON: I was just going to ask	03:20:19	4 THE COURT: Okay. So, let me just check the
03:17:31	5 Ms. Fernands if she has a fully redacted version. I don't	03:20:28	5 definitions here.
03:17:33	6 have a paper copy with me.	03:21:17	6 Now, we had a discovery dispute some time ago,
03:17:34	7 THE COURT: Right. Got it.	03:21:27	7 and we were discussing stuff that occurred after the
03:17:36	8 MS. MORRISON: If she has one, that would be	03:21:36	8 expiration of the patent. Do you remember what stuff we
03:17:37	9 very helpful.	03:21:41	9 were discussing?
03:17:39	10 MS. FERNANDS: I have Exhibit H to your	03:21:42	10 MS. MORRISON: I believe, Your Honor, and I'm
03:17:41	11 Complaint.	03:21:44	11 sure Ms. Fernands will correct me if I have it wrong, but I
03:17:41	12 MS. MORRISON: Thank you. Thank you so much.	03:21:48	12 believe that we were discussing whether Sarepta needed to
03:17:43	13 THE COURT: So, I'm just curious, Ms. Fernands.	03:21:53	13 produce its forecasts for sales of the ultimate gene therapy
03:17:55	14 So, I'm looking at the Table of Contents under Article VIII,	03:22:01	14 product for after the expiration of the patent --
03:17:58	15 and there's in what I have and what's in the public version	03:22:07	15 THE COURT: Okay.
03:18:03	16 an 8.4, and an 8.86 and an 8.8.	03:22:09	16 MS. MORRISON: -- as well as some other things.
03:18:08	17 And when I look at the -- going to where	03:22:10	17 But I think that was the main event.
03:18:12	18 Ms. Morrison's directed, I notice that there's an 8.5 and an	03:22:12	18 MS. FERNANDS: I think the main thrust was
03:18:18	19 8.7. And I'm just wondering why they're not in the Table of	03:22:13	19 Sarepta's projections generally for any of the final
03:18:23	20 Contents.	03:22:15	20 products, the gene therapy products. And we were ordered to
03:18:23	21 MS. FERNANDS: I do not know the answer to that	03:22:18	21 produce the adopted and approved projections from the point
03:18:26	22 question, but I hadn't noticed that. And you are correct.	03:22:21	22 of hypothetical negotiation to the present.
03:18:38	23 THE COURT: Okay. Well, I guess we can hold	03:22:23	23 And Sarepta then did produce a number of
03:18:41	24 that thought.	03:22:25	24 spreadsheets for both the assumptions underlying them and
03:18:42	25 So, Ms. Morrison.	03:22:30	25 the spreadsheets for a period of three years with Sarepta's
14		16	
03:18:44	1 MS. FERNANDS: I'm sorry. This is the executed	03:22:33	1 projections in them.
03:18:46	2 version, Your Honor. I don't know why --	03:22:35	2 THE COURT: Okay. And are those things, those
03:18:47	3 THE COURT: Probably a lot of last-minute	03:22:37	3 projections, are those things that your damages expert used?
03:18:50	4 changes.	03:22:41	4 MS. MORRISON: Yes.
03:18:50	5 All right. So, you were directing me to 8.4; is	03:22:42	5 THE COURT: Okay. Well, I'd have to say,
03:18:53	6 that right, or 8.41?	03:22:46	6 looking at 8.4.1A and B, I have difficulty thinking that
03:18:55	7 MS. MORRISON: Yes, 8.4.1 is the first place I	03:22:57	7 those help any. They certainly don't have any numbers in
03:18:59	8 would direct Your Honor. That Section 8.4 is entitled	03:23:01	8 them. So, that's tentatively what I think about that.
03:19:06	9 "Demand Forecast Plans."	03:23:06	9 Why don't you try another one.
03:19:06	10 THE COURT: Right. And then, because I'm	03:23:08	10 MS. MORRISON: Sure, Your Honor. So, the next
03:19:09	11 working on the assumption that if it's not in yellow, I can	03:23:09	11 one, and I mentioned this earlier, is the Joint Global
03:19:12	12 say it out loud, 8.4.1 is "Details."	03:23:13	12 Development Plan, which is the schedule to the agreement.
03:19:15	13 MS. MORRISON: Correct, Your Honor.	03:23:15	13 It's Schedule 4.3.1. So, I expect that will be at the very
03:19:16	14 THE COURT: And hold on. Let me just read it	03:23:21	14 back, Your Honor, but again, it's not attached to the
03:19:20	15 for a minute.	03:23:22	15 version that --
03:19:46	16 So, are you expecting there to be numbers of	03:23:23	16 THE COURT: 4.3.1, "Joint Global Development
03:19:49	17 some kind in these paragraphs?	03:23:26	17 Plan." I see it.
03:19:50	18 MS. MORRISON: Your Honor, it's very difficult	03:23:27	18 MS. MORRISON: Yes, Your Honor.
03:19:51	19 for me to tell because in the fully redacted version, it	03:23:28	19 THE COURT: Or, I mean, I see the schedule. Ah,
03:19:54	20 simply has an asterisk. Your Honor can't see that from	03:24:37	20 okay. Development -- Global Development Plan.
03:19:57	21 here. I apologize. I don't know why I'm holding it up.	03:26:16	21 Ms. Fernands, I'm looking at a page that has 20
03:20:00	22 But it simply has an asterisk.	03:26:20	22 at the bottom in this, what I think is all part of this one
03:20:02	23 So, again, this is one of those things that if	03:26:26	23 schedule, which there seems to have numbers.
03:20:03	24 there were numbers there, it could potentially be very	03:26:37	24 Have you found what I'm talking about?
03:20:07	25 relevant to Sarepta's expectation of what it and Roche would	03:26:39	25 MS. FERNANDS: Yes, I found what you're talking

03:26:40 **1** about.

03:26:40 **2** THE COURT: Is that something that's been

03:26:42 **3** otherwise produced?

03:26:43 **4** MS. FERNANDS: I think, to the extent that type

03:26:49 **5** of information has come to fruition in reality, it is

03:26:53 **6** reported in the 10Ks.

03:26:57 **7** THE COURT: So, it does seem that there's

03:27:27 **8** certainly costs and expenses on that in the next couple of

03:27:34 **9** pages that are probably, in some at least general sense,

03:27:52 **10** relevant to expected profits down the road; right?

03:27:55 **11** MS. FERNANDS: I think to the extent any of this

03:27:58 **12** is relevant, it would be captured in the adopted and

03:28:03 **13** approved projections that were produced. I don't think this

03:28:10 **14** instance -- this -- and sort of this cost information, I

03:28:14 **15** think, does not contain the types of projections that I

03:28:18 **16** understand Ms. Morrison to be expecting, which I think is

03:28:22 **17** sort of more of the sales and a sales-type projection which

03:28:26 **18** I don't think is at all in this document and that we have

03:28:29 **19** produced, again, through the adopted and approved

03:28:33 **20** projections.

03:28:34 **21** THE COURT: Ms. Morrison.

03:28:34 **22** MS. MORRISON: I think what we're looking for is

03:28:37 **23** any information that goes to Sarepta's sort of, for lack of

03:28:42 **24** a better word, state of mind at the time of the hypothetical

03:28:46 **25** negotiation. I, obviously, haven't seen this document.

03:28:49 **1** It's completely missing from the public version.

03:28:52 **2** But to the extent it has any sort of projection

03:28:55 **3** about costs, about volumes, about anything like that, I'm

03:29:03 **4** operating from a place of lack of knowledge because I

03:29:06 **5** haven't seen the document. But that might be relevant to

03:29:11 **6** our damages analysis because it would be relevant to what

03:29:14 **7** Sarepta would be willing to pay to get a license from

03:29:19 **8** Regenxbio.

03:29:19 **9** And so, without being able to see the document,

03:29:23 **10** I can't fully answer Your Honor's questions.

03:29:27 **11** THE COURT: Okay. All right.

03:29:32 **12** So, let's just hold that thought. Give me a

03:29:35 **13** third one.

03:29:36 **14** MS. FERNANDS: Before we move on, may I speak to

03:29:40 **15** the rest of that, Your Honor, because I think --

03:29:41 **16** THE COURT: Sure.

03:29:41 **17** MS. FERNANDS: -- even if you're looking at

03:29:43 **18** starting at Page 20, which I would argue they have

03:29:46 **19** information, to the extent relevant in other ways,

03:29:48 **20** everything up to Page 20, I think even from a cursory

03:29:50 **21** review, you can see has nothing to do with financials. And

03:29:54 **22** I would -- so, clearly not relevant to what we're talking

03:29:59 **23** about here for purposes of damages.

03:30:00 **24** THE COURT: Well, so what is your point here?

03:30:02 **25** That if I go wild and ask you to produce this, I should just

03:30:06 **1** ask you to produce Pages 20 to 22?

03:30:11 **2** MS. FERNANDS: I hope I'm not arguing against

03:30:13 **3** myself here, because I think it is all irrelevant, but yes,

03:30:16 **4** if you were to think that any of it is relevant, everything

03:30:21 **5** up to Page 20 should not be included.

03:30:23 **6** MS. MORRISON: And, Your Honor, I guess just to

03:30:25 **7** respond to that, we're operating from a place of lack of

03:30:29 **8** knowledge. So, what Sarepta believes is relevant may be

03:30:32 **9** different than what Regenxbio believes is relevant. And so,

03:30:37 **10** we don't see the -- there's a Protective Order in this case.

03:30:41 **11** We would agree that no one but the lawyers at Fish &

03:30:45 **12** Richardson and the lawyers for Penn would be able to see

03:30:48 **13** this agreement. That would be it.

03:30:49 **14** So, there's not a commercial risk to Sarepta to

03:30:52 **15** letting us look at this and determine whether there's things

03:30:56 **16** in there that our damages expert thinks are relevant. We

03:30:59 **17** can deal with the commercial risk, but there's little or no

03:31:03 **18** risk to allowing us to see the agreement to Sarepta.

03:31:08 **19** THE COURT: Okay. So, what's your third choice?

03:31:11 **20** MS. MORRISON: So, let me see. The other one is

03:31:26 **21** also -- there's also another schedule that several sections

03:31:34 **22** of the agreement refer to. It's Schedule 1.263. And it's

03:31:43 **23** entitled --

03:31:43 **24** THE COURT: Okay. Right. I think it's -- I saw

03:31:46 **25** it while I was leafing through trying to find the one we

03:31:49 **1** were just looking at. That's another one where the schedule

03:31:52 **2** isn't actually on the list in the Table of Contents.

03:31:54 **3** MS. MORRISON: It's not, Your Honor.

03:31:55 **4** THE COURT: But I've got it here. Let me just

03:31:58 **5** see whether I've got the first page of it.

03:32:01 **6** MS. MORRISON: And, Your Honor, the reason we

03:32:03 **7** think it might be relevant is there's definitions throughout

03:32:06 **8** the agreement of commercial supply agreement, development

03:32:10 **9** supply agreement and supply agreements that refer to this

03:32:14 **10** schedule as containing corresponding quantity agreements.

03:32:19 **11** THE COURT: Hold on just a minute.

03:32:23 **12** MS. MORRISON: Excuse me. I misspoke.

03:32:25 **13** Corresponding quality agreements fulfilling the requirements

03:32:28 **14** and so on.

03:32:49 **15** THE COURT: Yeah, on the surface, I don't see

03:32:58 **16** much here.

03:33:09 **17** All right. So, why don't we do this. Why don't

03:33:13 **18** we just take a short break, all right, and I'll be back.

03:33:16 **19** DEPUTY CLERK: All rise.

03:33:17 **20** (Recess was taken.)

03:45:30 **21** DEPUTY CLERK: All rise.

03:45:32 **22** THE COURT: All right. Be seated.

03:45:35 **23** So, part of what's public in here seemed to me

03:45:47 **24** to be -- well, actually, let me just ask.

03:45:51 **25** Ms. Morrison, you said your expert used this in

<p style="text-align: center;">21</p> <p>03:45:59 1 their opening report. Can you give me some hint as what</p> <p>03:46:12 2 they were using as public information? What sort of things</p> <p>03:46:15 3 were they using in the unredacted portions?</p> <p>03:46:18 4 MS. MORRISON: So, I think I can give you a</p> <p>03:46:24 5 general idea of what he was using. In general, he was using</p> <p>03:46:29 6 the portions of -- the unredacted portions that he could see</p> <p>03:46:34 7 to describe what Sarepta's position would have been at the</p> <p>03:46:39 8 time of the hypothetical negotiation.</p> <p>03:46:41 9 So, in other words, they had just made this very</p> <p>03:46:43 10 large deal with Roche. They would have been looking forward</p> <p>03:46:46 11 to certain payments and milestones based on the deal with</p> <p>03:46:50 12 Roche. We don't have the full scope of that because I think</p> <p>03:46:53 13 perhaps some of it is in the parts that are missing exactly</p> <p>03:46:56 14 what was coming forward.</p> <p>03:46:58 15 But the expert's theory, at a high level -- and</p> <p>03:47:02 16 please don't hold me to this, Your Honor, if I don't have it</p> <p>03:47:06 17 exactly right. I am certainly not an economist. But that</p> <p>03:47:10 18 Sarepta at the time of the hypothetical negotiation would</p> <p>03:47:13 19 have effectively had two choices.</p> <p>03:47:16 20 They could have either taken a license and</p> <p>03:47:18 21 continued with development because their product required</p> <p>03:47:21 22 the patented cultured host cell -- in order to continue the</p> <p>03:47:24 23 development, they needed the patented cultured host cells,</p> <p>03:47:28 24 or they would have had to stop and wait for the patent to</p> <p>03:47:31 25 expire.</p>	<p style="text-align: center;">23</p> <p>03:48:57 1 MS. MORRISON: Perhaps Ms. Fernands can correct</p> <p>03:48:58 2 me if I've gotten the science wrong there, but that does not</p> <p>03:49:02 3 have anything to do with the cultured host cells in this</p> <p>03:49:05 4 case.</p> <p>03:49:05 5 And I believe the same is true for the</p> <p>03:49:07 6 gene-editing piece. Neither of those are related to the</p> <p>03:49:12 7 cultured host cells.</p> <p>03:49:13 8 THE COURT: So, the things in the agreement that</p> <p>03:49:15 9 talk about, for lack of a better word, progress payments for</p> <p>03:49:34 10 various milestones, is your expert able to tell that one of</p> <p>03:49:42 11 these is the SRP one as opposed to the other ones?</p> <p>03:49:48 12 MS. MORRISON: So, I'm not a hundred percent</p> <p>03:49:50 13 sure. I believe our understanding is that at least that</p> <p>03:49:55 14 upfront payment was for -- related to the development of</p> <p>03:50:00 15 SRP-9001 using the patented cultured host cells, but I</p> <p>03:50:05 16 believe we're missing some of the information. I believe.</p> <p>03:50:08 17 And, again, Your Honor, I may not have this</p> <p>03:50:10 18 exactly right, but to be able to delineate that exactly</p> <p>03:50:14 19 because some of that information is redacted, I believe.</p> <p>03:50:18 20 But, again, I can't see what's redacted.</p> <p>03:50:20 21 THE COURT: Okay. Thank you.</p> <p>03:50:22 22 Is there anything more you want to say,</p> <p>03:50:24 23 Ms. Fernands?</p> <p>03:50:24 24 MS. FERNANDS: I think to the extent the expert</p> <p>03:50:27 25 is relying on this, there is -- the upfronts, as you said,</p>
<p style="text-align: center;">22</p> <p>03:47:32 1 And so, what would they have been thinking</p> <p>03:47:33 2 about? And the Roche agreement formed part of that of what</p> <p>03:47:37 3 they would have been thinking about in considering the cost</p> <p>03:47:39 4 it would have been to stop that development.</p> <p>03:47:41 5 THE COURT: So, there's a very large number that</p> <p>03:47:44 6 appears to be unredacted as kind of like the upfront</p> <p>03:47:48 7 payment; right? Is that part of --</p> <p>03:47:50 8 MS. MORRISON: That's part of what he relied on,</p> <p>03:47:52 9 yes, Your Honor.</p> <p>03:47:52 10 THE COURT: And the agreement, is it the case,</p> <p>03:48:03 11 your understanding, your expert's understanding, that large</p> <p>03:48:09 12 number, when it's talking about gene splicing or exon, are</p> <p>03:48:15 13 those things that grow out of, in your theory, you know, the</p> <p>03:48:21 14 use of your cultured cells or are they just completely --</p> <p>03:48:24 15 MS. MORRISON: No.</p> <p>03:48:24 16 THE COURT: -- things that Sarepta has free</p> <p>03:48:30 17 license to, you know, make as much money as they can from</p> <p>03:48:35 18 it?</p> <p>03:48:35 19 MS. MORRISON: If I understand it correctly,</p> <p>03:48:38 20 Your Honor, the exon-skipping drug -- Sarepta has a marketed</p> <p>03:48:43 21 product that does not use the cultured host cells and is not</p> <p>03:48:47 22 implicated in this case that is used to treat Duchenne</p> <p>03:48:54 23 Muscular Dystrophy that is -- it's called an exon-skipping</p> <p>03:48:56 24 drug.</p> <p>03:48:56 25 THE COURT: Okay.</p>	<p style="text-align: center;">24</p> <p>03:50:30 1 were public. To the extent that any other payment gets made</p> <p>03:50:33 2 in the future, that would be reported. None have been.</p> <p>03:50:37 3 And their expert has not relied on this as being</p> <p>03:50:42 4 comparable. So, I don't think the details of the specific,</p> <p>03:50:45 5 whether it be a percentage or the milestone for a particular</p> <p>03:50:49 6 event, would be relevant because this is not relied on as a</p> <p>03:50:52 7 comparable license. It's relied on for Sarepta's state of</p> <p>03:50:55 8 mind which, again, I think that the projections that we</p> <p>03:50:58 9 provided would provide that information without having to</p> <p>03:51:01 10 produce this agreement.</p> <p>03:51:02 11 MS. MORRISON: We, obviously, don't agree, Your</p> <p>03:51:10 12 Honor, or we wouldn't be here asking for production of the</p> <p>03:51:12 13 agreement. At least that there is a reasonable likelihood</p> <p>03:51:15 14 that there are things in there that are relevant to</p> <p>03:51:18 15 Sarepta's state of mind that would inform the hypothetical</p> <p>03:51:23 16 negotiation.</p> <p>03:51:23 17 THE COURT: Okay. And so, the big number, the</p> <p>03:51:50 18 upfront payment, which I believe is three-quarters of a</p> <p>03:51:54 19 billion dollars, maybe that's not big in the pharmaceutical</p> <p>03:51:57 20 world, but it seems big to me. Your belief is that that is</p> <p>03:52:06 21 basically for the access to the SRP materials; right?</p> <p>03:52:14 22 MS. MORRISON: Yes, the SRP-9001 made using the</p> <p>03:52:17 23 cultured host cells.</p> <p>03:52:19 24 THE COURT: And your expert, his calculations</p> <p>03:52:31 25 here, I suppose, are for a reasonable royalty?</p>

03:52:35 **1** MS. MORRISON: Yeah, it's for a lump sum payment
 03:52:37 **2** that the parties would have agreed to, but yes, it's not a
 03:52:40 **3** lost profits analysis. It's a reasonable royalty analysis
 03:52:42 **4** under Georgia-Pacific.
 03:52:43 **5** THE COURT: And does the amount of money that
 03:52:45 **6** changed hands in this agreement play into that reasonable
 03:52:50 **7** royalty analysis in a quantitative way?
 03:52:55 **8** MS. MORRISON: It does, Your Honor, only in
 03:52:57 **9** that -- not in the sense that our expert certainly is not
 03:53:02 **10** saying, well, Sarepta is going to get paid "X" dollars by
 03:53:05 **11** Roche, and so they would have paid "Y" dollars. It's not
 03:53:08 **12** that direct.
 03:53:09 **13** But it's a -- and, again, I don't want to
 03:53:13 **14** misquote. I don't have his report memorized. But it goes
 03:53:17 **15** to several things.
 03:53:18 **16** It goes to Sarepta's state of mind as to the
 03:53:21 **17** value of the market as to what they would be leaving on the
 03:53:24 **18** table if they didn't take a license. And so, how much the
 03:53:28 **19** license was worth to them.
 03:53:30 **20** It goes to at least those sorts of issues, but
 03:53:33 **21** it's not a direct quote.
 03:53:35 **22** THE COURT: Well, I guess what I'm wondering is
 03:53:42 **23** so, if there are, you know, progress payments -- you know,
 03:53:45 **24** let's say, just hypothetically here, but somewhere in this
 03:53:52 **25** agreement it says, Okay, and there will be \$10 million every

03:54:00 **1** month, you know, for the next five years, or it says \$5
 03:54:05 **2** million, or it says a hundred million dollars, how is that
 03:54:08 **3** going to affect anything?
 03:54:10 **4** MS. MORRISON: So, I think what it would impact,
 03:54:12 **5** Your Honor, is, again, I can only talk in hypotheticals
 03:54:16 **6** because I can't see the agreement. But if there were, for
 03:54:19 **7** example, a provision that said there's going to be a
 03:54:22 **8** progress payment of \$10 million for every month so long as
 03:54:27 **9** you, Sarepta, are actually making progress towards
 03:54:30 **10** developing SRP-9001, without a license, excuse me, to the
 03:54:35 **11** patented cultured host cell, our damages theory is Sarepta
 03:54:39 **12** would have had to stop development and wait for the patent
 03:54:42 **13** to expire, which is a term of about 35 months.
 03:54:45 **14** And so, Sarepta would be thinking, Well, if we
 03:54:48 **15** don't take this license, we're going to lose 35 months of
 03:54:51 **16** \$10 million a month, and that's really valuable to us. And
 03:54:55 **17** so, it would go into how Sarepta is valuing that license --
 03:54:59 **18** THE COURT: Right.
 03:54:59 **19** MS. MORRISON: -- if there were such a
 03:55:01 **20** provision.
 03:55:01 **21** THE COURT: But, you know, once you've said
 03:55:06 **22** \$750 million, you know, whether it's over the next 35 months
 03:55:12 **23** another \$750 million or whether it's, you know, a mere \$100
 03:55:17 **24** million, or if that's not being factored into how much they
 03:55:26 **25** pay, what difference does it make?

03:55:28 **1** MS. MORRISON: Well, so it would be factored
 03:55:30 **2** into how much they pay. And, Your Honor, it's difficult for
 03:55:32 **3** me to -- again, I'm not an economist, but essentially our
 03:55:36 **4** expert's damages number or his model looks at: What is the
 03:55:42 **5** value of that 35 months to Sarepta and what is the value of
 03:55:45 **6** that 35 months to Regenxbio? And how would they come into
 03:55:49 **7** this and bargain between them to divide that value
 03:55:53 **8** effectively?
 03:55:54 **9** And so, if there are more payments in this
 03:55:57 **10** agreement that Sarepta would receive during that 35 months,
 03:56:01 **11** that would add to the value of the license to Regenxbio.
 03:56:06 **12** And I'm sure that our damages expert could explain this far
 03:56:10 **13** better than I can, because I'm not an economist, and he'll
 03:56:13 **14** have graphs and models, to the extent that we get that far
 03:56:17 **15** in this case. But it would factor into the value of the
 03:56:23 **16** license to Sarepta.
 03:56:45 **17** THE COURT: What is your expert's bottom line
 03:56:50 **18** lump sum number at this point?
 03:56:52 **19** MS. MORRISON: I'm going to misquote it, Your
 03:56:55 **20** Honor, but it's approximately -- it's just a little over
 03:56:58 **21** [REDACTED]. Because he valued that delay and something
 03:57:06 **22** again, I'm not going to get the number right, but the value
 03:57:08 **23** of that delay to Sarepta that if they had to wait the
 03:57:12 **24** 35 months, it would have been on the order of [REDACTED]
 [REDACTED] I'm forgetting, but it was [REDACTED]

03:57:19 **1** [REDACTED] the loss Sarepta would have incurred if they had
 03:57:23 **2** had to wait, according to his models.
 03:57:26 **3** I'm quite sure Sarepta will disagree with that
 03:57:28 **4** valuation.
 03:57:28 **5** THE COURT: Yeah, I think that's a reasonable
 03:57:30 **6** certainty.
 03:57:30 **7** MS. MORRISON: Yeah.
 03:57:58 **8** THE COURT: So, does your economist write at
 03:58:00 **9** this point, have sort of like a range of values based on, I
 03:58:11 **10** don't know, how much they were expecting to get paid over
 03:58:13 **11** the 35 months? I mean, do you have any information at all
 03:58:18 **12** about -- other than the upfront lump sum, is there any other
 03:58:22 **13** public information as to what's in the agreement, or do you
 03:58:26 **14** have any other information about how much revenue this was
 03:58:31 **15** supposed to generate?
 03:58:32 **16** MS. MORRISON: Yes, from Sarepta's projections,
 03:58:34 **17** we do.
 03:58:35 **18** THE COURT: Uh-huh.
 03:58:40 **19** MS. MORRISON: But I have no way of knowing
 03:58:42 **20** whether those projections include -- those projections are
 03:58:46 **21** Sarepta's -- at least my understanding of them is they are
 03:58:48 **22** Sarepta's own U.S. sales. I don't know that they include --
 03:58:54 **23** at least my understanding of them is that they do not
 03:58:57 **24** include these kind of -- payments from Roche.
 03:59:01 **25** And so, that would be additional value that



<p>03:59:04 1 Sarepta -- potential -- if there is, as Your Honor</p> <p>03:59:07 2 hypothesized, a provision that would require Sarepta to make</p> <p>03:59:12 3 progress in order to earn additional payments, that is not</p> <p>03:59:15 4 currently accounted for in our damages model, because we are</p> <p>03:59:18 5 unaware of such payments. And that is not -- the Sarepta</p> <p>03:59:22 6 forecasts are based on their own U.S. sales.</p> <p>03:59:24 7 THE COURT: Do you have any comment on that,</p> <p>03:59:31 8 Ms. Fernands?</p> <p>03:59:32 9 MS. FERNANDS: I believe the forecasts -- I</p> <p>03:59:35 10 don't know if that's entirely accurate, and I believe that</p> <p>03:59:38 11 the forecasts have tabs for a variety of issues, including a</p> <p>03:59:46 12 Roche tab, although I cannot speak to the details of what is</p> <p>03:59:49 13 in that tab. But I do know that that tab is in the</p> <p>03:59:51 14 projections that were produced.</p> <p>03:59:52 15 I don't think -- I think what I'm hearing is a</p> <p>03:59:55 16 lot of the agreement might, which is a lot of speculation --</p> <p>03:59:59 17 where what we have is it is definitely not asserted that</p> <p>04:00:04 18 it's comparable, and they know the general overall value</p> <p>04:00:08 19 from public information. So, the details are not relevant.</p> <p>04:00:16 20 MS. MORRISON: And, again, Your Honor, we just</p> <p>04:00:17 21 disagree, and I think Rule 26, right, does not require that</p> <p>04:00:22 22 the information that we're seeking during discovery ends up</p> <p>04:00:26 23 being admissible as evidence or that we necessarily have to</p> <p>04:00:30 24 rely on it. And the reason I'm saying might is because, of</p> <p>04:00:33 25 course, I haven't seen these provisions because Sarepta has</p>	<p>04:01:49 1 Mr. Estepan's deposition.</p> <p>04:01:52 2 THE COURT: All right. As much fun as this is</p> <p>04:01:54 3 for the two of you, Ms. Fernands, Page 69, there's</p> <p>04:02:00 4 Table 9.4.1 that's called "Lead Product Regulatory</p> <p>04:02:04 5 Milestones." That's in the public version.</p> <p>04:02:09 6 Is the lead product here SRP-9001?</p> <p>04:02:13 7 MS. FERNANDS: Yes, Your Honor.</p> <p>04:02:13 8 THE COURT: And the public version says,</p> <p>04:02:20 9 "Achievement of lead product regulatory milestone event,"</p> <p>04:02:23 10 and then there's some redacted information. And part of the</p> <p>04:02:29 11 redacted information doesn't provide based on various events</p> <p>04:02:38 12 or what seem like decently large numbers of payments.</p> <p>04:02:48 13 Why isn't that relevant information?</p> <p>04:02:51 14 MS. FERNANDS: I think, again, that isn't</p> <p>04:02:53 15 relevant information because let's just step back. This is</p> <p>04:02:56 16 about the final products, ex-US, and not about cultured host</p> <p>04:03:03 17 cells.</p> <p>04:03:03 18 And so, just to start on the broadest brush</p> <p>04:03:08 19 strokes, this agreement should not be relevant to damages.</p> <p>04:03:11 20 To the extent it's relevant to damages as the larger picture</p> <p>04:03:16 21 that -- their only argument is that it's Sarepta's state of</p> <p>04:03:20 22 mind about continuing development and what that value is for</p> <p>04:03:23 23 which Sarepta's projections should be adequate.</p> <p>04:03:28 24 These details about what would be paid for ex-US</p> <p>04:03:32 25 activities for the final products are far removed from the</p>
<p>04:00:36 1 refused to produce them.</p> <p>04:00:39 2 And so, Sarepta, at this point, appears to be</p> <p>04:00:43 3 attempting to hold us to a standard of we have to show that</p> <p>04:00:46 4 the things that we haven't seen are going to be admissible</p> <p>04:00:50 5 or end up being relevant to the damages analysis. All I can</p> <p>04:00:53 6 say is, based on this agreement, which was marked at</p> <p>04:00:56 7 multiple depositions, it was, in fact, cited in multiple</p> <p>04:01:00 8 interrogatory responses on comparable licenses and on our</p> <p>04:01:04 9 damages analysis, and then it was cited in our expert</p> <p>04:01:07 10 reports.</p> <p>04:01:08 11 We clearly think that it's relevant to the</p> <p>04:01:11 12 damages -- at least to the damages issues, and I really</p> <p>04:01:13 13 haven't touched on the safe harbor issues. But it's</p> <p>04:01:17 14 certainly relevant to the damages issues.</p> <p>04:01:19 15 MS. FERNANDS: I don't believe that either of</p> <p>04:01:20 16 the interrogatory responses or the damages report asserts</p> <p>04:01:23 17 this as a comparable license.</p> <p>04:01:24 18 MS. MORRISON: Interrogatory 17, which asks for</p> <p>04:01:28 19 comparable licenses, this response was or, excuse me, this</p> <p>04:01:33 20 document was cited in Interrogatory Number 17.</p> <p>04:01:37 21 Now, again --</p> <p>04:01:37 22 MS. FERNANDS: Well, what is the Bates number</p> <p>04:01:39 23 that it was cited as?</p> <p>04:01:41 24 MS. MORRISON: It was cited as deposition</p> <p>04:01:43 25 exhibit -- recited as a deposition exhibit to</p>	<p>04:03:36 1 value of the cultured host cell that they assert that</p> <p>04:03:41 2 Sarepta would be infringing.</p> <p>04:04:01 3 MS. MORRISON: And I'm happy to address that if</p> <p>04:04:03 4 you --</p> <p>04:04:03 5 THE COURT: No, no. So, I take it in the parts</p> <p>04:04:12 6 here where it talks about payments relating to gene therapy</p> <p>04:04:20 7 product or gene editing, you don't care about those; right?</p> <p>04:04:29 8 MS. MORRISON: Well, gene editing, I think</p> <p>04:04:32 9 that's right.</p> <p>04:04:33 10 Gene therapy product, I don't know how that's</p> <p>04:04:35 11 defined. I believe that might be relevant because the</p> <p>04:04:39 12 accused cultured host cells are used to make more than</p> <p>04:04:45 13 SRP-9001. They are used to make other gene therapy products</p> <p>04:04:48 14 by Sarepta. And so, perhaps those would also be relevant.</p> <p>04:04:54 15 But I would agree with you on gene editing and</p> <p>04:04:58 16 exon skipping, those are not relevant.</p> <p>04:05:00 17 THE COURT: All right. Okay.</p> <p>04:05:03 18 Well, so here's what I'm going to do. With the</p> <p>04:05:12 19 understanding that this agreement is Attorneys' Eyes Only,</p> <p>04:05:16 20 which I take it must include the expert, I'm going to order</p> <p>04:05:26 21 its production. I do so because I think, based on what I've</p> <p>04:05:35 22 heard, that the lead product regulatory information that's</p> <p>04:05:40 23 in here, to the extent that I see it on, for example,</p> <p>04:05:46 24 Page 69, and Page 70, and Page 72 and Page 74, that while I</p> <p>04:06:08 25 think the relationship between payments for final products,</p>

04:06:16 **1** you know, are not direct evidence of value of the cultured
 04:06:23 **2** cells or the production method, you know, there's both
 04:06:31 **3** quantitative and qualitative.
 04:06:33 **4** And it may be that some of this is similar or
 04:06:37 **5** different, I don't know, to the actual -- to the projections
 04:06:46 **6** that were made. Maybe the projections should be roughly the
 04:06:50 **7** same because -- well, you would think they would be somewhat
 04:06:56 **8** close.
 04:06:56 **9** But I think that for an expert to be relying on
 04:07:04 **10** a license, even for state of mind, it's a big handicap not
 04:07:11 **11** to have the entire agreement available to him so that he can
 04:07:21 **12** decide what there is in it that is relevant to his
 04:07:28 **13** undertaking.
 04:07:29 **14** And, you know, I think the lead -- it seems to
 04:07:35 **15** me at least reasonable to say that the lead product
 04:07:38 **16** information is relevant to his undertaking, which is partly
 04:07:44 **17** based on the fact that in the expert report, he's managed to
 04:07:51 **18** use the agreement as part of his support for his opinions.
 04:08:02 **19** And so, having a high degree of confidence in
 04:08:09 **20** the Confidentiality Order, and I think it should be
 04:08:23 **21** produced.
 04:08:25 **22** MS. FERNANDS: May we produce in a redacted form
 04:08:27 **23** with the exon skipping and gene editing all removed?
 04:08:31 **24** MS. MORRISON: Your Honor, we don't have any
 04:08:32 **25** objection to that other than our concern that as long as


04:08:36 **1** that is all that's removed, I don't have a concern about
 04:08:39 **2** that. And as long as --
 04:08:41 **3** THE COURT: Okay.
 04:08:41 **4** MS. MORRISON: As long as our expert isn't going
 04:08:43 **5** to be cross-examined with, You didn't have the complete
 04:08:47 **6** agreement, that's my only concern, to be honest. We're not
 04:08:52 **7** going to use those parts, but --
 04:08:54 **8** THE COURT: All right. Well, it seems to me,
 04:08:56 **9** then, that you should redact those parts, that is,
 04:09:00 **10** essentially the pricing parts. The rest of it --
 04:09:09 **11** MS. FERNANDS: With respect to the schedules,
 04:09:11 **12** may I also ask with the schedules that we focused on that
 04:09:16 **13** were, as you saw, only three pages that are arguably
 04:09:19 **14** financial in the schedule that they pointed to, and the rest
 04:09:22 **15** goes to what I'd say technical or clinical.
 04:09:29 **16** THE COURT: No, I think the technical and
 04:09:38 **17** clinical, I would think isn't going to make too much
 04:09:41 **18** difference to a damages expert because I'm assuming he's
 04:09:46 **19** probably not a whole lot better qualified than me to make
 04:09:49 **20** sense of it. But I think, you know, basically the redaction
 04:10:05 **21** of the exon skipping and the gene splicing, everyone agrees
 04:10:15 **22** those dollars are just irrelevant. And we're not going to
 04:10:19 **23** have arguments later on about whether or not you redacted
 04:10:22 **24** too much, and I'd prefer to avoid that.
 04:10:25 **25** I prefer to avoid having -- that it's real clear

04:10:29 **1** what has been redacted. And so, basically the dollar
 04:10:36 **2** figures for these things that are not the lead product or
 04:10:44 **3** the gene therapy product, yeah, you can do that, but
 04:10:49 **4** otherwise, you ought to give over a clean agreement.
 04:10:54 **5** Okay?
 04:10:54 **6** MS. FERNANDS: May I ask, and I hope this won't
 04:10:56 **7** be controversial, schedule 11.6.2 is a Roche internal
 04:11:01 **8** document concerning Roche compliance policies. It's a
 04:11:05 **9** rather long document. It is -- I think there's -- I think
 04:11:10 **10** it's listed in the -- 11.6.2 is listed in the public version
 04:11:15 **11** of schedules, I think. But, Your Honor, you can see in the
 04:11:18 **12** version that you have that it is a document with a Roche
 04:11:22 **13** header.
 04:11:22 **14** THE COURT: It's 100 percent redacted; right?
 04:11:25 **15** MS. FERNANDS: It was 100 percent redacted.
 04:11:27 **16** Only the title was in the public.
 04:11:28 **17** THE COURT: It seems --
 04:11:34 **18** MS. MORRISON: Without having seen it, it's
 04:11:35 **19** difficult for me to say, but I will accept Ms. Fernands'
 04:11:40 **20** representation.
 04:11:40 **21** THE COURT: Well, I mean, just looking at it, I
 04:11:42 **22** mean, it really is like a statement of corporate policy that
 04:11:45 **23** has nothing to do with -- I think this has nothing to do
 04:11:51 **24** with this contract in particular; right?
 04:11:53 **25** MS. FERNANDS: That is my understanding, and it

04:11:55 **1** certainly is not even my client's information. It's our
 04:11:58 **2** co-development partner's information.
 04:12:00 **3** THE COURT: All right. Well, I understand --
 04:12:02 **4** so, you can redact that. Okay?
 04:12:08 **5** All right. And I assume you'll be able to
 04:12:11 **6** produce -- to do those two, the one little set of redactions
 04:12:15 **7** for dollar figures and the Roche corporate policy and
 04:12:20 **8** produce this, you know, like by the end of the week?
 04:12:23 **9** MS. FERNANDS: Yes, we should be able to produce
 04:12:26 **10** it by the end of the week, Your Honor.
 04:12:27 **11** THE COURT: Okay. Well, thank you. It's an
 04:12:29 **12** interesting problem you all have.
 04:12:30 **13** We'll be in recess.
 04:12:32 **14** DEPUTY CLERK: All rise.
 04:12:32 **15** THE COURT: The transcript will serve as my
 04:12:35 **16** Order.
17 (Court was recessed at 4:12 p.m.)
18 I hereby certify the foregoing is a true and
19 accurate transcript from my stenographic notes in the
20 proceeding.
21 /s/ Heather M. Triozzi
22 Certified Merit and Real-Time Reporter
23 U.S. District Court
24
25

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